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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BLANCO, JAVIER G	
ART UNIT	PAPER NUMBER
3774	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,819	MOLZ, FRED J.	
	Examiner	Art Unit	
	JAVIER G. BLANCO	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-24,27-34,63-71,73-85 and 87-90* is/are pending in the application.

4a) Of the above claim(s) *4,5 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 6-15, 17-24,27-34,63-71,73-85 and 87-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2008 has been entered.

Response to Amendment

2. Applicant's amendment of claims 3-6, 8-10, 19, 20, 22-24, 27-30, 33, 34, 63, 66, 67, 69, 73-77, 82-85, 87, and 88 in the reply filed on January 30, 2008 is acknowledged.

3. Applicant's cancellation of claims 1, 2, 25, 26, 72, and 86 in the reply filed on January 30, 2008 is acknowledged.

4. The declaration filed on January 30, 2008 under 37 CFR 1.131 is sufficient to overcome the Jackson (US 7,195,643 B2) reference.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 3, 6-12, 15, 17, 19-21, 23, 24, 27-33, 63, 64, 66-71, 73-76, 78-80, 82-85, 87, and 89 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kohrs (US 6,224,631 B1). Referring to Figures 1-20, Kohrs discloses a spinal implant assembly, comprising:

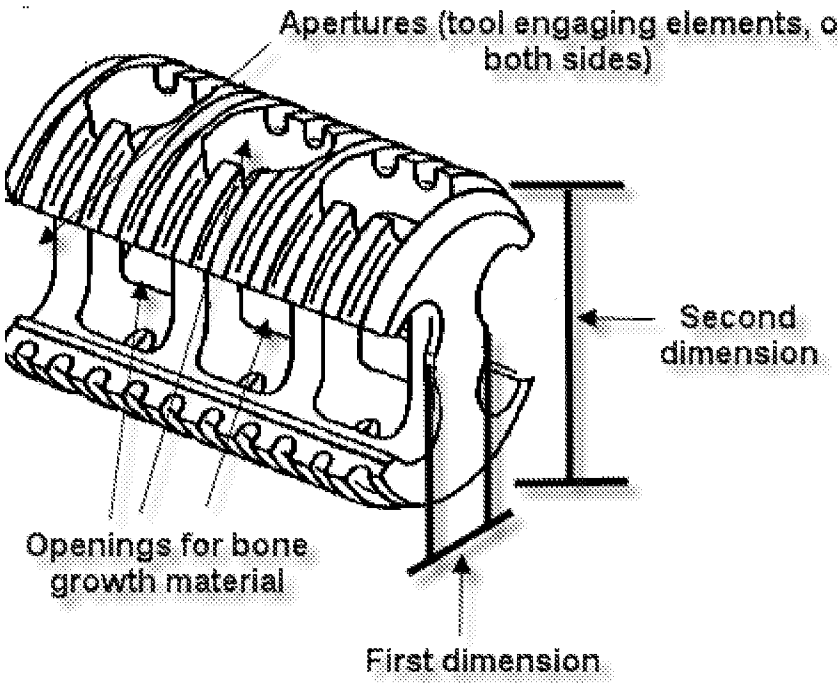
a. A device comprising a fusion cage (10) *adapted for insertion* into an intervertebral space between an adjacent pair of vertebral bodies, said device extending along a longitudinal axis and defining a primary transverse dimension and a secondary transverse dimension, said secondary transverse dimension *sized for insertion* into the intervertebral space, said primary transverse dimension sized greater than said secondary transverse dimension and corresponding to a select height of said intervertebral space, wherein the fusion cage further comprises rounded transitional surfaces and apertures (tool engaging elements) to receive projection portions **(see representation of Figure 17 of Kohrs '631, below)**;

b. A bone growth promoting material (e.g., bone growth matrix) positioned within said fusion cage to facilitate fusion with the adjacent vertebral bodies; and

c. An elongate member (Figure 17: elongate member 500, comprises a plurality of bone anchors 526, 527 and plate-shaped projection/interlock 506 comprising projection portions 523, 524) *sized to span* the intervertebral space and a plurality of bone anchors (526, 527) extending transversely from said elongate member and into engagement with the adjacent vertebral bodies. As seen in Figure 17, said spinal implant is engaged with said elongate member *to allow* selective rotation of said spinal implant relative to said elongate member about said longitudinal axis, said selective rotation of said spinal implant *serving to transition* said first transverse dimension to said second transverse dimension along said select height of the intervertebral space.

Regarding the limitation/clause "*to establish* said select height of the intervertebral space and *to maintain* said select height as said device is rotated/transitioned (e.g., the device is rotated, screwed, and/or manipulated during surgery) about said longitudinal axis *to align* said primary transverse dimension along said select height *to thereby provide* controlled compression of said device", **(i)** it does not provide structure to the spinal construct, and **(ii)** it does not provide structural relationship between the fusion device and the "elongate member".

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).



7. Claims 3, 8-12, 17, 18, 24, 28-32, 34, 63-71, 73-85, and 87-90 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bonutti (US 6,099,531 A).

Referring to Figures 10, 14-16, and 24, Bonutti discloses a spinal implant assembly (see column 2, lines 25-34), comprising:

a. A device comprising a porous fusion cage 44 (see columns 10, 11: "hollow wedge member") *adapted for insertion* into an intervertebral space between an adjacent pair of vertebral bodies (see column 2, lines 25-34), said device extending along a longitudinal axis and defining a primary transverse dimension and a secondary transverse dimension, said secondary transverse dimension *sized for insertion* into the intervertebral space, said primary transverse dimension sized greater than said secondary transverse dimension and corresponding to a select height of said intervertebral space (clearly seen in Figures 14 and 15);

b. A bone growth promoting material (110) positioned within said fusion cage to facilitate fusion with the adjacent vertebral bodies (see columns 10, 11: "hollow wedge member"), wherein said bone growth promoting material comprises a bone morphogenic protein (see column 10, lines 9-24); and

c. A plate (Figure 16: end portion 50d) having first (144) and second (146) end portions and a plurality of bone screws (70, 72) extending transversely from said plate. As seen in Figures 14-16, said spinal implant is engaged with said elongate member *to allow* selective rotation of said spinal implant relative to said elongate member about said longitudinal axis, said selective rotation of said spinal implant *serving to transition* said first transverse dimension to said second transverse dimension along said select height of the intervertebral space. Alternatively, the "elongate member" could be broadly interpreted as the combination of end portion 50b/ 60b

(Figure 10) and the elongated tool engaging said end portion, and the "bone anchor" could be broadly interpreted as either bone screws 70, 72 and/or frictional forces between the implant, the "elongate member", and the vertebral surfaces. The "interlock" as claimed could be broadly interpreted as aperture 140 receiving a manipulation tool, and/or the frictional forces between the implant, the "elongate member", and the vertebral surfaces.

Regarding the limitation/clause "*to establish* said select height of the intervertebral space and *to maintain* said select height as said device is rotated/transitioned (e.g., the device is rotated, screwed, and/or manipulated during surgery) about said longitudinal axis *to align* said primary transverse dimension along said select height *to thereby provide* controlled compression of said device", **(i)** it does not provide structure to the spinal construct, and **(ii)** it does not provide structural relationship between the fusion device and the "elongate member".

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

8. Claims 8-15, 19-23, 63, 66, and 69-71 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Crozet et al. (US 6,375,683 B1).

Referring to Figures 1-8, Crozet et al. disclose a spinal construct comprising:

(i) A spinal implant comprising an intervertebral fusion device/cage including a hollow interior (**first interpretation:** the implant, when finally assembled, has a hollow interior/space between upper and lower plates; **second interpretation:** hollow interior comprised by 35; **third interpretation:** hollow interior/space comprised by 24) in communication with one or more openings (e.g., sides of implant, slots 15a, 15b, etc.), said implant extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension (Figure 8: element 30; Figures 1-7: elements 30a, 30b) and corresponding to a select height of an intervertebral space (see column 4, lines 45-50 and lines 54-67); and

(ii) An elongate member (Figure 8: element 100 and element 200; Figures 1-7: bearing elements 20a, 20b and intermediate plate 11).

As shown in Figures 1-8 (see column 4, lines 45-50 and lines 54-67), the implant includes a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension, and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension, wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. Also, the implant has a rectangular transverse cross section, and includes rounded corners to facilitate rotation. The spinal construct further includes an interlock, including at least one aperture (bores 15 and/or bore(s) 34) and at least one projection (screw(s) 40 and nut(s) 50). As an alternative interpretation, the interlock could also be the frictional interaction/engagement between the implant and the elongate member (see column 5, lines 27-33), wherein surfaces 32 and 32' or 33 and 33' are the projections, grooves 12a and 22 or 12b and 22 are the apertures,

and screw 40 (or screws 40) is the fastener. An axially facing portion of the implant defines at least two tool-engaging elements (sockets 35) *sized and configured for engagement* with corresponding portions of a manipulation tool (see column 4, lines 58-61). The elongate member defines a pair of arcuate slots (24 and/or 14) positioned diametrically opposite one another relative to the longitudinal axis.

Regarding the limitation/clause "*to establish* said select height of the intervertebral space and *to maintain* said select height as said device is rotated/transitioned (e.g., the device is rotated, screwed, and/or manipulated during surgery) about said longitudinal axis *to align* said primary transverse dimension along said select height *to thereby provide* controlled compression of said device", **(i)** it does not provide structure to the spinal construct, and **(ii)** it does not provide structural relationship between the fusion device and the "elongate member".

With regard to the statement of intended use and other functional statements (e.g., configured *to promote*, etc.), they do not impose any structural limitations on the claims distinguishable over Crozet et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

9. Claims 8-12, 23, 24, 27, 63, and 67-71 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dixon et al. (US PG Pub No 2002/0107519 A1).

Referring to Figures 1-10, Dixon et al. disclose a spinal construct comprising:

(i) A fusion implant (plates 31 and/or dowel 53) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension and corresponding to a select height of an intervertebral space (Figures 4 and 5; see paragraph 0030 and paragraph 0041); and

(ii) An elongate member (flange 33; flange 33 and tube 34).

As shown in Figures 3a-3d, the implant (plates 31 and/or dowel 53) includes a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension, and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension, wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. Also, the implant includes a substantially rectangular transverse cross section and rounded corners to facilitate rotation.

Alternatively (as indicated above), dowel 53 is the spinal implant comprising a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension (distance of the thread on one surface to the thread on an opposite surface), and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension (distance of the groove on one surface to the groove on an opposite surface), wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. As clearly seen in Figures 8 and 10, and disclosed in paragraph

0039 and paragraph 0044, dowel 53 comprises opening 54, grooves between the threads, and/or is porous. Dowel 53 may be made from bone, biodegradable material, bioabsorbable material, allograft material, or autograft material, which materials are known for being porous, therefore meeting the "one or more openings".

As clearly seen in Figures 8 and 10, and disclosed in paragraph 0039 and paragraph 0044, the spinal implant is engaged with the elongated member. The spinal construct further includes an interlock (see Figure 2), including at least one aperture (flange slots 32 or arcuate flanges 46) and at least one projection (an end of the implant is broadly interpreted as projecting). The elongate member comprises top and bottom openings 37 to accept fasteners (screws 36). A tool (see Figure 5) is used to rotate the implant from said first transverse dimension to said second transverse dimension.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738